

CLAIMS

1. A spore which is genetically modified with genetic code comprising at
2 least one genetic construct encoding a therapeutically active compound and a
targeting sequence or a vegetative cell protein
2. A spore as claimed in Claim 1 characterised in that the therapeutically
2 active compound is an antigen or a medicament or a precursor to an antigen or
a medicament.
3. A spore as claimed in Claim 1 or Claim 2 characterised in that the gene
2 construct is a chimeric gene.
4. A spore as claimed in any one of the preceding Claims characterised in
2 that the spore is of Bacillus or Clostridia.
5. A spore as claimed in any one of the preceding Claims characterised in
2 that the genetic modification is accomplished by transformation of a mother
cell using a vector containing the gene construct and then inducing the mother
4 cell to produce spores as defined in any one of the preceding Claims.
6. A spore as claimed in any one of the preceding Claims characterised in
2 that the gene construct is under the control of one or more of, each or
independently, an inducible promoter, a promoter or a strong promoter or
4 modified promoter.
7. A spore as claimed in Claim 6 characterised in that the gene construct
2 has an enhancer element or an upstream activator sequence associated with it.

8. A spore as claimed in any one of the preceding Claims characterised in
2 that the construct comprises an inducible expression system.
9. A spore as claimed in any one of the preceding Claims characterised in
2 that the spore germinates in the duodenum and/or the jejunum of an intestinal tract of a human or animal body.
10. A spore as claimed in any one of the preceding Claims characterised in
2 that the therapeutically active compound is an antigen which, in use, is adapted to elicit an immune response.
11. A spore as claimed in Claim 10 characterised in that the antigen is at
2 least a fragment of tetanus toxin fragment C or labile toxin B sub unit.
12. A spore as claimed in any one of the preceding Claims characterised in
2 that the protein is a protein that is expressed in the cell barrier.
13. A spore as claimed in any one of the preceding Claims characterised in
2 that the protein is expressed all the time in a vegetative cell.
14. A spore as claimed in Claim 13 characterised in that the protein is
2 OppA or rrnO.
15. A spore as claimed in any one of Claims 1 to 12 characterised in that
2 the protein is expressed intermittently in a vegetative cell.
16. A spore as claimed in any one of Claims 1 to 11 characterised in that
2 the protein is a soluble cytoplasmic vegetative cell protein.

17. A spore as claimed in Claim 16 characterised in that the protein is *rrnO*.
18. A spore as claimed in Claim 16 or Claim 17 characterised in that the
2 genetic construct of the soluble cytoplasmic protein wholly or partially
comprises a signal sequence.
19. A spore as claimed in any one of Claims 1 to 11 characterised in that
2 the signal sequence is adapted to target the therapeutically active compound to
a specific part of the vegetative cell.
20. A spore as claimed in Claim 19 characterised in that the signal
2 sequence directs the therapeutically active compound for secretion (preferably
active secretion, more preferably Type I, Type II or Type III secretion), or for
4 post-translational processing by a vegetative cell (preferably glycosylation).
21. A spore as claimed in any one of the preceding Claims characterised in
2 that the therapeutically active compound is an antigen precursor which is one
or more enzymes capable of transforming a biological precursors, such that
4 upon germination said one or more enzymes are expressed and synthesise one
or more antigens by transformation of a said biological precursor.
22. A spore as claimed in Claim 21 characterised in that the biological
2 precursor is a hormone, a steroid hormone, a painkiller or a pro-drug.
23. A spore as claimed in any one of Claims 1 to 20 wherein the
2 therapeutically active compound is a medicament which is a protein, a vaccine
or an endorphin.

24. A spore as defined in any one of the preceding Claims characterised in
2 that it is for use in treatment of a medical condition, preferably the medical
condition is inflammation, pain, a hormonal imbalance and/or an intestinal
4 disorder.

25. A composition comprising at least two different spores as defined in
2 any one of the preceding Claims characterised in that said at least two
different spores express at least two different therapeutically active
4 compounds.

26. A composition as defined in Claim 25 characterised in that the
2 composition further comprises a pharmaceutically acceptable excipient or
carrier.

27. A composition comprising a spore as defined in any one of claims 1 to
2 24 in association with a pharmaceutically acceptable excipient or carrier.

28. A composition as defined in any one of Claims 25 to 27 for use in
2 treatment of a medical condition, preferably the medical condition is
inflammation, pain, a hormonal imbalance and/or an intestinal disorder.

29. Use of a spore as defined in any one of claims 1 to 24 in the
2 manufacture of a medicament for use in the treatment of a medical condition,
preferably the medical condition is inflammation, pain, a hormonal imbalance
4 and/or an intestinal disorder.

30. A method of medical treatment, which method comprises the steps of
2 a) administering a spore as defined in any one of claims 1 to 24 to a
human or animal in need of medical treatment;

- 4 b) said spore germinating into a vegetative cell in the intestinal tract;
- 6 c) said vegetative cell expressing a therapeutically active compound for use in the medical treatment.

31. A method as claimed in Claim 30 characterised in that the spore is
2 administered orally, intra-nasally or rectally.